Supplementary Table 3. Key Safety Results in the Non-Asian Countries Subgroup of GEMINI 1 Patients: Induction Phase

Parameter	Placebo[a]	Vedolizumab (cohort 1)[a]	Vedolizumab (cohort 2)	Vedolizumab (combined)
No.	120	196	466	662
Any AE	59 (49)	84 (43)	223 (48)	307 (46)
Drug-related AE	21 (18)	32 (16)	96 (21)	128 (19)
AE resulting in study discontinuation	3 (3)	0	8 (2)	8 (1)
SAE	7 (6)	5 (3)	19 (4)	24 (4)
Serious infection AE	3 (3)	1 (< 1)	3 (< 1)	4 (< 1)
Drug-related SAE	2 (2)	1 (< 1)	3 (< 1)	4 (< 1)
Serious AE resulting in study discontinuation	3 (3)	0	6 (1)	6 (< 1)
Deaths	0	0	1 (< 1)	1 (< 1)

Values are presented as number (%).
Placebo and vedolizumab (cohort 1) = the groups that were part of the double-blind induction phase (induction intent-to-treat (ITT) population); Vedolizumab (cohort 2) = additional patients were enrolled to meet the maintenance phase sample size requirements and received open-label vedolizumab (induction safety population only); Vedolizumab combined = all patients that received vedolizumab during the induction phase.
[a]Data for the ITT population.
AE, adverse event; SAE, serious AE.